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| APPLICATION NO.            | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------|----------------------|---------------------|------------------|
| 10/767,550                 | 01/29/2004  | Richard A. Gambale   | B0410/7269D2        | 5097             |
| 22832                      | 7590        | 01/31/2005           | EXAMINER            |                  |
| KIRKPATRICK & LOCKHART LLP |             |                      | KENNEDY, SHARON E   |                  |
| 75 STATE STREET            |             |                      | ART UNIT            |                  |
| BOSTON, MA 02109-1808      |             |                      | PAPER NUMBER        |                  |
|                            |             |                      | 3762                |                  |
| DATE MAILED: 01/31/2005    |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/767,550

Applicant(s)

GAMBALE ET AL.

Examiner

Sharon Kennedy

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 and 31 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/2/04; 1/29/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

Art Unit: 3762

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

#### ***Ex parte Quayle***

This application is in condition for allowance except for the following formal matters: See below. A correction to the disclosure required.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213. A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

#### ***Specification***

The disclosure is objected to because of the following informalities: It incorporates essential material by reference to an unpublished pending application. See 37 CFR 1.57c. The essential material incorporated herein by reference is the steerable delivery catheter. Applicant incorporates USSN 09/073,118 to show the steerable aspects of the catheter. However, USSN 09/073,118 is not published, and is therefor not a publication. Essential material may no longer be incorporated by reference to an unpublished pending application. Further, the steerable aspects of the catheter are important because it distinguishes the claims from the prior art.

Appropriate correction is required.

#### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the steerable catheter

Art Unit: 3762

must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 30 is objected to because of the following informalities: In line 5 of claim 30, "the" (second occurrence) should be changed to --of--. Appropriate correction is required.

### ***Allowable Subject Matter***

Claims 30, 31 are allowed.

Art Unit: 3762

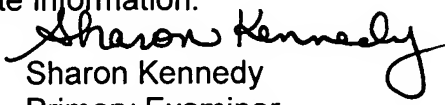
The following is a statement of reasons for the indication of allowable subject matter: Applicant has already uncovered the closest prior art and adequately defined the invention. The claims require that the catheter be steerable, in combination with the other claimed aspects. Kaldany, US 5,906,599 is relevant to claim 30, but fails to disclose a device that would be steerable. The Hussein patents are the most important (US 6,080,163, 6,053,924, 5,971,993 and 5,810,836 and), however, none of these patents show a steerable catheter, and the devices could not perform the method as claimed. Further, it does not appear that the elongate shaft is slidable through the lumen of the delivery catheter. The sharp distal end of the Hussein could not be retracted into the delivery catheter to enable the catheter to be navigated through the patient's vessels into the left ventricle. Accordingly, the claims are allowable.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571/272-4955.

Information regarding the status of an application may be obtained by going to [www.uspto.gov](http://www.uspto.gov), clicking on "Status &IFW", entering the application number, and then clicking on one of the tabs to retrieve the appropriate information.

  
Sharon Kennedy  
Primary Examiner  
Art Unit 3762

Sek